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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/223,634	12/31/1998	RANDOLPH J. NOELLE	012712 - 652	1304

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/223,634	Applicant(s) NOGUE ET AL.
	Examiner GAMBEL	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/12/01

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 13-26

4a) Of the above claim(s) ___ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 13-26

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 6/12/02 (Paper No. 12), has been entered.

Claims 1, 2, 5-10 and 12 have been canceled.
Claims 3, 4 and 11 have been canceled previously

Claims 13-26 have been added.

It is noted that applicant's newly added claims encompass two autoimmune diseases (i.e. oophoritis and thyroiditis; not "thyroluitis"; applicant is required to amend claim 22 to correct this), previously not claimed. In the interest of compact prosecution, this Office Action will address these newly added limitations.

Therefore, claims 13-26 are under consideration.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 6/12/02 (Paper No. 12). The rejections of record can be found in the previous Office Action (Paper No. 15).

3. Applicant's arguments, filed 6/12/02 (Paper No. 12), have been fully considered but are not found convincing essentially for the reasons of record and those set forth herein.

Applicant argues that the prior art of record does not suggest inhibition of T cell-mediated (?) tissue destruction or a T cell mediated autoimmune disease(s) using a gp39 antagonist. Applicant further submit that inherency requires certainty, not merely a possibility.

In contrast to applicant's assertions, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosures reiterated herein for applicant's convenience.

See Bristol-Myers Squibb Company v. Ben Venue Laboratories 00-1304 (CAFC 4/20/01).

For example, preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims; case does not present situation in which new use of process should be considered limiting because it distinguishes process over prior art and voluntary amendment adding preamble language, made after examiner indicated that claims were allowable, does not create material limitation.

The Court held that the preamble language "for reducing hematologic toxicity" was non-limiting and merely express a purpose of reducing hematologic toxicity relative to the toxicity experience by a patient undergoing a twenty-four infusion.

Also, In re Hirao 190 USPQ 15, 16-17, (CCPA 1976) held that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim. The express dosage amount are material claim limitations, the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.

Applicant's arguments are not found persuasive for the reasons of record and set forth herein.

4. Newly submitted claims 13-16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 5,683,693) (see entire document) for the reasons of record. Noelle et al. teach the use of gp39-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 5-7, Antibodies) to treat the autoimmune disease diabetes (see entire document, including column 11, Uses of the Methods of Invention). Given the inhibitory properties of such gp39-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including diabetes with gp39-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

5. Newly submitted claims 13-16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document). Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases such as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes (see column 11, paragraph 5). Given the inhibitory properties of such 5C8-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes with of 5C8-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

6. Newly submitted claims 13 and 17 are rejected under 35 U.S.C. § 102(e) as being anticipated by Armitage et al. (U.S. Patent No. 6,264,951) (see entire document). Armitage et al. teach the use of CD40 antagonists, including CD40 and CD40/Fc to teat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes, (see entire document, including columns 10-11, overlapping paragraph). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes with CD40 antagonists, including CD40 and CD40/Fc. A species will anticipate a claim to a genus. See MPEP 2131.02.

7. Newly submitted claims 13-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816) AND/OR Armitage et al. (U.S. Patent No. 6,264,951) in view of
Schieven (U.S. Patent No. 5,565,491), Stull et al. (Cell. Immunol. 117: 188-198, 1988) and Flynn et al. (Cell. Immunol. 122: 377-390, 1989) with respect to thyroiditis AND/OR
and Tung et al. (Clin. Immunol. Immunopathol. 73: 275-282, 1994) and Rabinowe et al. (Am J. Med. 81: 347-350, 1986) with respect to oophoritis.

Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases such as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes (see column 11, paragraph 5).

Armitage et al. teach the use of CD40 antagonists, including CD40 and CD40/Fc to treat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes, (see entire document, including columns 10-11, overlapping paragraph).

Lederman et al. and Armitage et al. differ from the claimed methods by not disclosing certain autoimmune diseases, such as thyroiditis and oophoritis, encompassed by the claimed methods.

Schieven teach the use of phosphotyrosine inhibitors can be used to control proliferation of B cells in which the downregulation of the immune response is desired, as for the treatment of autoimmune diseases such as rheumatoid arthritis, Hashimoto's thyroiditis and SLE as well as other autoimmune diseases (see entire document, including column 17, paragraph 2). Schieven teach that phosphotyrosine inhibitors can be used to inhibit antibody responses mediated by the CD40L gp39 (see column 19, paragraph 2).

Stull et al. teach the prevention and reversal of experimental thyroiditis with anti-L3T4 antibody (see entire document, including Abstract and Discussion) by targeting the same or nearly the same cells targeted by the gp39 antagonists taught by the primary references. .Stull et al. teach that targeting or blocking the activation of T helper cells might be effective in therapy of autoimmune diseases in humans (see Discussion, including the last paragraph).

Likewise, Flynn et al. teach that the depletion of L3T4+ and Lyt-2+ cells by antibodies alters the development of experimental thyroiditis (see entire document, including Abstract and Discussion). Flynn et al. Teach that helper T cells are responsible for the transfer and development of thyroiditis (see Abstract and Discussion). Again, Flynn et al. Is targeting the same or the same cells targeted by the gp39 antagonists taught by the primary references.

Tung teach that $CD4^+$ T cells readily transfer autoimmune oophoritis in experimental models and that activated T cells can stimulate B cells and provide autoantibody responses (see entire document).

Rabinowe et al. teach that T cells contribute to the immune dysfunction in autoimmune oophoritis in humans and that this can explain the benefit from immuonosuppressive corticosteroid therapy (see entire document).

Given the teachings of Lederman et al. and Armitage et al. to inhibit several autoimmune diseases with CD40:CD40L antagonists combined with the teachings of Schieven to target B cell responses and antibody responses mediated by CD40L as well as targeting helper T cells to treat thyroiditis referenced by Stull et al. and Flynn would be useful in treating autoimmune diseases; one of ordinary skill in the art at the time the invention was made would have targeted a number of non-multiple sclerosis autoimmune diseases such as thyroiditis encompassed by the claimed invention with CD40:CD40L antagonists such as CD40L-specific antibodies or soluble CD40 alone or in combination with standard therapy. Given the teachings of Tung concerning the contribution of T cells to autoimmune oophoritis as well as the teaching of Rabinowe et al. that T cells contribute to the immune dysfunction in autoimmune oophoritis in humans and that this can explain the benefit from immuonosuppressive corticosteroid therapy, one of ordinary skill in the art would have been motivated to target oophoritis with CD40:CD40L inhibitors as taught by Lederman et al. and Armitage et al. to treat an autoimmune disease such as oophoritis with an expectation of success at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
August 29, 2002